

Exhibit A

1 IN THE UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 AT CHARLESTON

4 IN RE: ETHICON, INC.) Master File No.
5 PELVIC REPAIR SYSTEM) 2:12-MD-02327
6 PRODUCTS LIABILITY) MDL 2327
7 LITIGATION)
8) JOSEPH R. GOODWIN
9 _____) U.S. DISTRICT JUDGE
10)
11 DIANNE M. BELLEW,)
12)
13) Plaintiff,
14)
15) Plaintiff,
16)
17) -vs-)
18) No. 13-CV-22473
19)
20 ETHICON, INC., ET AL.,)
21)
22) Defendants.
23)
24 _____))
25

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13
14 VIDEOTAPED DEPOSITION OF
15
16 DENISE M. ELSER, M.D.
17
18 September 16, 2014
19
20 Chicago, Illinois
21
22
23
24
25

1 IFU?

2 A. No, because fibromyalgia was discussed
3 in the surgeons monograph.

4 Q. Do all doctors see the surgeons
5 monograph before they use the Prolift?

6 A. No, but I think it's available if
7 they -- if they want to see it.

8 MR. SLATER: Move to strike after "no."

9 BY MR. SLATER:

10 Q. Do you understand the purpose of the IFU
11 under federal regulations?

12 A. No. I understand how it's used in -- in
13 clinical practice.

14 Q. But you don't know the purpose of the
15 IFU in terms of why it's put into the box with the
16 product?

17 A. Correct.

18 Q. When you told the FDA that rigorous
19 effective trials of native tissue repair comparing
20 to vaginal mesh would be required, did you mean
21 what you said?

22 MR. COMBS: Object to the form.

23 BY THE WITNESS:

24 A. I was presenting the ACOG opinion from
25 the committee. This was not my personal -- these

1 colleagues, they rely on conferences, literature.
2 There's much more goes into it than the IFU
3 stating --

4 Q. So, from your perspective, from your
5 perspective in your opinion, the purpose of the IFU
6 is not to provide the risks and complications known
7 to Ethicon regarding the Prolift to physicians.
8 That's your perspective and your opinion, correct?

9 A. That's my opinion and the Instructions
10 for Use, how do I use this in the OR. That is how
11 it's going -- I believe will be accepted by most
12 surgeons. And you just gave me -- I want to do
13 this study now. I'm going to survey all kinds of
14 gynecologic surgeons to see if they even know what
15 an IFU is.

16 MR. SLATER: Move to strike from "that"
17 forward.

18 BY MR. SLATER:

19 Q. Let me ask you this. If Ethicon knew
20 that some women would suffer complications from the
21 Prolift that would be severe and that despite
22 multiple operations the woman could not be safely
23 and effectively treated and would be left with
24 permanent chronic pain, if Ethicon knew that, would
25 you agree with me they needed to get that

1 Q. Again, in forming your opinions, you
2 don't know what Ethicon's obligations were to warn,
3 correct?

4 A. Correct.

5 Q. So, your opinions are not based on what
6 Ethicon was obligated to do from any source, right?

7 MR. COMBS: Object to the form.

8 BY THE WITNESS:

9 A. I -- my opinion is that as a surgeon who
10 has -- who does pelvic reconstructive surgery and
11 using mesh that what I expect the company put in
12 the IFU to help me understand how to do pelvic
13 reconstructive surgery with mesh may not include
14 every single complication.

15 MR. SLATER: Move to strike.

16 BY MR. SLATER:

17 Q. All I'm saying is the opinions you're
18 offering about the warnings are not based on any
19 standard whatsoever as to what Ethicon was required
20 to do because you don't know what they were
21 required to do, right?

22 A. No, I'm commenting on what the average
23 pelvic surgeon needs to know.

24 MR. SLATER: Move to strike.

25 BY MR. SLATER:

1 Q. Is the answer to my question yes?

2 MR. COMBS: Object to form.

3 BY THE WITNESS:

4 A. Yes.

5 BY MR. SLATER:

6 Q. I'd like you to assume -- no, I'll
7 withdraw that. Just give me one second. I'm
8 almost done.

9 I didn't finish with your materials in
10 your report. Let's go to the end of your report,
11 the last two pages.

12 The second-to-last page of your report
13 of Attachment B is a list of expert reports,
14 depositions, other and medical records.

15 Do you see that?

16 A. Yes.

17 Q. With regards to those categories of
18 documents, that's all you saw. And, of course, the
19 medical records go over to the next page. You
20 didn't see any other expert reports, depositions or
21 medical records, correct?

22 A. I have since seen some more depositions
23 and expert reports.

24 Q. Did you read or rely on any of those
25 depositions or expert reports?